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JAN 31 2007

Atty. Dkt. No. NEKT/0019

**REMARKS**

This is intended as a full and complete response to the Office Action dated November 2, 2006, having a shortened statutory period for response set to expire on February 2, 2007. Please reconsider the claims pending in the application for reasons discussed below.

The Specification has been amended to clarify the invention. The amendment to the Specification does not include any new matter.

Claims 60-68, 70-75, and 83-86 remain pending in the application. Claims 60-68 and 70-75 stand rejected by the Examiner. Please reconsider the claims for the reasons presented below.

Claims 63, 64, 68, 72, and 86 have been amended to clarify implicit aspects of the invention. These amendments are not in response to the cited prior art or directed to the patentability of the invention; therefore the amendment is not intended to narrow the claims or otherwise limit the scope of equivalents thereof. Entry of these amendments and reconsideration of the claims is respectfully requested.

Applicant respectfully appreciates the Examiner withdrawing the 35 U.S.C § 102 and 35 U.S.C § 103 rejections.

**Double Patenting**

The provisional obviousness-type double patenting rejection of claim 54 as being unpatentable over claim 29 of copending Application No. 10/514,895 is maintained by the Examiner. However, claim 54 was cancelled by Amendment in the Request for Continued Examination filed September 22, 2006. Therefore this rejection is moot, and Applicant respectfully requests the withdrawal of the rejection.

Claims 60-68, 70-75, and 83-86 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of allowed U.S. Patent Application 11/006,464 (hereinafter '464). Applicant respectfully traverses the rejection.

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Claims 60-68, 70-75, and 83-86 are patentably distinct from later filed claim 1 of '464 as claim 1 recites elements not recited in claims 60-68, 70-75, and 83-86. For example, claim 1 recites co-introducing a first target substance in a first vehicle, and a second target in a second vehicle, while the instant claims recite an active substance and an oligomeric or polymeric material in a fluid vehicle. Furthermore, claim 1 recites the limitations that the second vehicle is immiscible with the first vehicle, and that contact between the first and second vehicle occurs a sufficiently short period of time before their dispersion by the anti-solvent fluid, as to allow only insignificant, if any, phase separation to occur between the two vehicles between their contact with one another and their dispersion. These limitations are not recited by claims 60-68, 70-75, and 83-86 of the instant case. Applicant respectfully requests the withdrawal of the rejection.

#### **Claim Rejections – 35 U.S.C. § 112**

Claims 60-68, 70-75, and 83-86 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the Application lacks written description for 1) the genus of "near critical or supercritical fluids," 2) the genus of "active substances," and 3) the genus of "polymeric materials." Applicant respectfully traverses the rejection.

With regards to 1) the genus of "near critical or supercritical fluids," the term modifies "anti-solvent" so that the recited claim element is "a near-critical or supercritical fluid anti-solvent." Support for this element can be found throughout the written description, such as on page 5 of the Specification as filed, lines 13-31 (describing a SEDS™ process wherein a supercritical or near critical fluid anti-solvent is used simultaneously both to disperse, and to extract a fluid vehicle from, a solution or suspension of a target substance).

In regards to 2) the genus of "active substances," the Examiner asserts that all of the active substances disclosed as useful in the invention are organic molecules of low molecular weight, which is not sufficient to provide written description for all active substances, the genus of which includes many materials which are not organic

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molecules of low molecular weight and includes inorganic salts, proteins, polymeric active substances, DNA, and RNA.

Support for "active substance" can be found throughout the written description, such as on page 7 of the Specification as filed, lines 14-24. For example, support is found for the substances cited by the Examiner: The substance may be monomeric or polymeric, organic (including organometallic) or inorganic, hydrophilic or hydrophobic. The substance may also be a larger molecule such as a polypeptide (proteins are polypeptides), an enzyme (enzymes are proteins), an antigen (a foreign protein, toxin, bacteria), or other biological material (DNA and RNA are biological materials). As such, a person of ordinary skill in the art would recognize that Applicant had possession of the term "active substance."

In regards to 3) the genus of "oligomeric or polymeric materials," the Examiner asserts that only a few of such materials are disclosed as being in the invention, and that this is not sufficient to show possession of a method including all oligomeric or polymeric materials.

Support for "oligomeric or polymeric materials" can be found throughout the written description, such as a plethora of oligomeric and polymeric materials (page 6, line 1 – page 7, line 14): Of the numerous oligomeric or polymeric materials disclosed as being useful in the invention a few are: polyethylene glycol, hydroxypropyl methyl cellulose, ethyl cellulose, polyvinyl pyrrolidone, traditional "natural" source materials, homo- and copolymers of hydroxy acids, acrylates, hydrated silicas, vinyl polymers, polymeric surfactants, phospholipids, carbohydrates, dendrimeric polymers, poly( $\epsilon$ -caprolactones), and poly(orthoester)s. As such, a person of ordinary skill in the art would recognize that Applicant had possession of the term "oligomeric or polymeric materials."

Withdrawal of the rejection is respectfully requested.

Claims 63, 64, 68, 72, and 86 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner asserts that the artisan would not know if a particular substance is a "derivative" of the claimed

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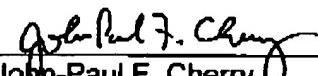
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materials. Claims 63, 64, 68, 72, and 86 have been amended to remove "derivatives thereof" from the claim language. Withdrawal of the rejection is respectfully requested.

Having addressed all issues set out in the Office Action, Applicant respectfully submits that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,

  
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